

disclosed as capable of use together, having different modes of operation, different functions or different effects." The example provided are a shoe and a locomotive bearing. Clearly, in the instant case, the claims are not so independent. We draw the Examiner's particular attention to MPEP 808.01 (Examiner note 1): "This form paragraph is to be used only when claims are presented to unrelated inventions, e.g., a necktie and a locomotive bearing." Clearly the Examiner has misapplied the rules of restriction in the instant case as all of the presented claims are related to the Universal Vector which allows for protein expression in chloroplasts to produce a variety of products of one's design, such as hormones, insecticidal resistance proteins, herbicide resistance proteins, synthetic protein polymers, and hybrid proteins. The use of the vector necessarily generates transformed chloroplasts and stably transformed plants. It should be noted that these transformed plants and chloroplasts are not mere intermediates, but are the products of the transformation process with the Universal Vector and lead to the production of a molecule of interest, e.g., selected proteins in the plants.

The Examiner states that the "inventions" involve "physiologically and biochemically divergent products and processes not required by any other." This is an overstatement which can be put into perspective using the Examiner's categories of alleged "inventions":

(a) "genes encoding a multitude of non-proteinaceous products and vectors comprising protein-encoding genes and chloroplast flanking sequences":

The Universal Vector, as claimed in claims 1 and 85 are drawn to producing a "molecule of interest." These molecules are a broad way of stating the products produced by recombinant DNA technology, namely RNA and protein. Claims 2 and 86 for example are narrower in scope as they are drawn to embodiments encoding a "peptide of interest." We respectfully submit that the claims are drawn to embodiments that are clearly related.

(b) "synthetic-base polymer genes, animal hormone-encoding genes, fusion protein-encoding genes, a multitude of isolated polypeptides, a multitude of isolated synthetic protein-base polymers, isolated animal hormones, transformed plants containing herbicide resistance genes, a process for using a vector comprising herbicide resistance genes and additional genes encoding a multitude of traits of interest, vectors comprising a multitude of structural genes and flanking DNA sequences, transformed plants containing insect resistance genes isolated DNA comprising chloroplast intergenic spacer regions":

The Universal Vector contains as an element of the expression cassette, a heterologous gene of interest. That is, as one of ordinary skill in the art would understand, a portion of DNA that encodes a polypeptide of interest. This DNA is expressed, through mRNA, and results in production of a protein. Such a protein may confer a detectable phenotype to the plant and may even be isolated. Examples of this include the overexpression of proteins for subsequent isolation (e.g. hormones, fusion proteins, synthetic protein-base polymers) or may be useful by simply conferring a trait to the plant itself (such as the production of proteins conferring herbicide or insecticide resistance). The point being that the Universal Vector allows for the production of a variety of products through a common mechanism and vector. The vector comprises flanking DNA sequences which are homologous to a spacer sequence of the target chloroplast genome, which sequence is conserved in the chloroplast genome of different plant species. These inventions are clearly more related than a necktie is to a locomotive bearing.

(c) "a vector comprising non-chloroplast flanking DNA and a non-protein-encoding gene, and a transformed chloroplast flanking DNA and genes encoding synthetic protein-base polymers."

The Universal Vector also has embodiments using non-chloroplast flanking DNA to impart stable transformation into a variety of plants. The arguments set forth above in (b) apply to these embodiments as well. We respectfully request withdrawal of the

restriction requirement as the inventions are not so unrelated as to be properly rejected under MPEP 806.04 and 808.01.

It should be noted here that the Examiner has designated claims 179 and 183 as having non-chloroplast flanking sequences (Group XIV). This is true. The Examiner also designates claims 184-186 (Group XV) as having non-chloroplast flanking sequences. This is not accurate. Claim 184 is dependent on claim 179 and is properly designated. However, claims 185-186 are ultimately dependent on Claim 2 or claim 86 which have chloroplast flanking sequences. We urge the Examiner to include these in a group which contains DNA flanking sequences which are homologous to a spacer sequence of the target chloroplast genome which is conserved in the chloroplast genome of different plant species.

If the Examiner sustains that the embodiments having non-chloroplast flanking sequences are distinct inventions, the Applicants would be willing to prosecute these claims (claims 179, 183 and 184) in a separate Application.

These Related Inventions Must Be Patentably Distinct to be Subject to Restriction Under MPEP 808.02:

When inventions are not independent and are related, they must be distinct in order to be properly subject to restriction, otherwise restriction is improper (See MPEP §806 (A-C)). The Examiner has indicated separate classes for Groups I-XV, and indicates that the claims are drawn to "distinct" inventions. However, as explained below, the inventions are not so distinct as to make restriction proper.

The Examiner notes that the claims fall into different classes. However, it should be noted that many of the main classes are the same for different groups, and that the groups differ in the subclass numbers. Groups II-III, IX, and XII, for example, are all classified in Class 800. Groups I, IV-V, XI and XV are all in Class 435. Groups XIII-XIV are all in Class 536, and Groups VI-VIII are in Class 530. It is not an automatic

restriction simply when claims are directed to different classes or subclasses. There must be a showing that the claims are distinct. Where different fields of search are indicated, these must in fact be pertinent to the type of subject matter covered by the claims. (See MPEP 808.02).

We respectfully submit that these claims are not so distinct as to be the basis of restriction. Examples of issued U.S. patents are easily found in which the field of search and Classification are these very Classes and Fields of Search. For example, we note that U.S. Patent No. 5,990,383 to Warren et al. (cover page enclosed for the Examiner's convenience) is classified in U.S. Classes, 800, 435, 530 and 536. These are the exact Classes noted by the Examiner for the instant claims. The Field of search in U.S. 5,990,383 were also 800, 435, 536 and 530. Clearly, subject matter of Classes 800, 435 and 536 and 530 are not so distinct. We respectfully request withdrawal of the requirement for restriction as such a requirement would treat the Applicant claims inconsistently with issued claims in other patents.

As another example, U.S. Patent No. 6,011,198 to Ko (front page enclosed for the Examiner's convenience) is listed in U.S. Classes: 800/205; 435 (various subclasses); and 536 (various subclasses). These are the same classes as those noted for the instant case for Groups I-V, and IX-XV. Again, it is clear that the subject matter of Classes 800, 435 and 536 are not so distinct.

The Specific Technical Relatedness of the Claims:

Turning now to the specific technical details of the Applicant claims, each of the Claims is drawn to the Universal Vector, or method employing the Universal Vector. The Universal Vector is an integrating expression vector which stably transforms the chloroplast of plants using DNA flanking sequences on an expression cassette that are

homologous to a spacer sequence of the target chloroplast genome that is conserved in the chloroplast of many plant species.

In the broadest claim, the vector may accommodate a gene target of interest and may be used to express a polypeptide of interest and can be used to express protein and non-protein molecules such as RNA (Claims 1 and 85). In the next broadest claim, heterologous DNA encoding a peptide of interest is claimed (base claim 2). It should be evident DNA may be inserted into the Universal Vector such that many different peptides of interest may be expressed. The fact remains that these claims are dependent forms of the parent claim which is the Universal Vector. For example, the expression of peptide A in the vector, or expression of peptide B in the vector does not alter the fact that it is the Universal Vector ("UV") that is the main feature of all of these claims. The embodiments share the features of chloroplast DNA flanking sequences that enable the vector to specifically integrate into a conserved region of the chloroplast genome.

As the Examiner notes, Claims 2-84, 86-96, 107, 118-119, 122, 168-169, and 171-176 are drawn to the Universal Vector which encodes a peptide, stably transformed plants, and a process for transforming a plants employing the UV. These vectors are used to produce a variety of peptides of interest. Group III claims (claims 97-99, 108-110 and 180-182) are drawn to the use of the Universal Vector to produce a synthetic peptide, and Group IV claims (claims 100-102 and 104-106) are drawn to a process for producing hormones using the UV. Group V claims (Claims 103 and 111-113) are drawn to a process for producing hybrid constructs of insulin-PBP. The claims in Groups VI, VII and VIII are drawn to the isolated proteins themselves (insulin, synthetic protein and hybrid proteins) formed by the process of expressing these proteins using the UV. The types of proteins in these groups is very limited in scope; i.e. synthetic proteins, insulin and hybrid proteins. Each of these proteins are identified in Class 350. Therefore, Groups III-VIII should be joined with Group II.

The Applicant also urges that Groups IX, X, XI and XII be joined as these groups are drawn to plants which have been transformed with a vector that encodes a resistance gene. Group IX contains claims drawn to herbicide resistance genes and Group XII contains claims drawn to insect resistance genes. Group X further comprises a second gene of interest in addition to an herbicide resistance gene. All of these claims are in Class 800. Group XI claims are drawn to specific vectors. These claims all are based on the UV. Therefore, we urge the Examiner to consider joining Groups IX-XII with Group II claims. As these claims are drawn to the single inventive concept of a base UV vector incorporating resistance, irrespective of the resistance.

Group XIII contains claims drawn to the isolated region of the chloroplast that are conserved among a multitude of plants. This region of the chloroplast is the region wherein the UV integrates and is an important aspect of the UV. Therefore we urge the Examiner to consider joining this group as well.

Conclusion

We strongly urge the Examiner to consider joining Groups I-XV into one for prosecution. However, we specifically urge the Examiner to at least join Groups I-XIII, and XV which the Applicant would elect for prosecution. Again the Examiner should reconsider re-assigning claims 185-186 to a group having a chloroplast flanking sequence.

However, in order to comply with the requirement for election even though the requirement be traversed, the Applicant elects Group II drawn to Universal Vectors encoding a peptide for stable integration, plants transformed therewith, and a process for obtaining these plants.

Reconsideration of the number of restrictions is requested and a prompt action on the merits is urged.



Respectfully submitted,

A handwritten signature in cursive script that reads "Gerard J. Weiser".

Gerard J. Weiser
Reg. No. 19,763
Attorney for Applicants

Date 1/10/00

(215) 751-2427

Attachments: US Patent No. 5,990,383 (first page only)
US Patent No. 6,011,198 (first page only)

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Certification Under 37 CFR 1.8

Date of Deposit January 10, 2000

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